

**UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION**

**IN RE: NATIONAL PRESCRIPTION  
OPIATE LITIGATION**

THIS DOCUMENT RELATES TO:

*Track Seven*

**MDL No. 2804  
Case No. 17-md-2804  
Judge Dan Aaron Polster**

**KROGER DEFENDANTS' OPPOSITION TO PLAINTIFF'S  
MOTION FOR PARTIAL SUMMARY JUDGMENT ON  
DEFENDANTS' DUTIES UNDER THE CONTROLLED SUBSTANCES ACT**

Defendants The Kroger Co., Kroger Limited Partnership I, and Kroger Limited Partnership II (collectively, "Defendants"), by and through counsel, respectfully move this court to deny Plaintiff's Motion for Partial Summary Judgment on Defendants' Duties Under the Controlled Substances Act [Doc. # 4881; Doc. # 2950] (hereinafter, the "Motion").

This Court should deny the Motion on both procedural and substantive grounds. Procedurally, the Motion cannot be granted under Federal Rule of Civil Procedure Rule 56(d) ("Rule 56"), 22 U.S.C. § 2201, or as an advisory opinion; therefore, any such attempt should be rejected. Substantively, Plaintiff misleadingly confuses prior rulings on distribution and dispensing duties and ignores subsequent rulings of clarification such that the relief sought, if granted, would render this Court's rulings inconsistent.

**I. The Relief Sought is Inappropriate for Summary Judgment.**

This Motion is procedurally improper for three reasons. First, it seeks resolution of only a portion of a claim – a fragment – which is impermissible under Rule 56. Second, the fragment of the claim on which Plaintiff seeks summary judgment is merely a legal contention, rendering this request one for a declaratory judgment. Plaintiff does not have standing to request a declaratory

judgment under the Controlled Substances Act (“CSA”) (21 U.S.C. § 801, *et seq.*) because the CSA does not provide for a private right of action. Third, because the Motion cannot be sought for a portion of a claim, and Plaintiff does not have standing to seek a declaratory judgment, the Motion is necessarily a request for an advisory opinion, which a federal court may not provide. As such, there is no appropriate reason for Plaintiff’s request. Rule 56(h) provides that a court may award sanctions for motions that are made without an appropriate basis.

By its Motion, Plaintiff seeks “partial” summary judgment on its claims. Plaintiff is correct that Rule 56 allows for this Court to rule on an issue or defense as opposed to the entirety of the case. Fed R. Civ. P. 56. However, Rule 56 may not be used to adjudicate a fragment of a claim. Here, Plaintiff seeks summary judgment on only the legal aspect of one of its claims, namely, the legal question of whether the CSA applies to pharmacies so as to create a legal duty. Motion, 1-2. Effectively, this is but a portion (the legal one) of a total claim (nuisance). When presented with requests for partial summary judgment, courts in the Sixth Circuit begin by analyzing a threshold question: “[W]hether it is a *proper* request for partial summary judgment—*i.e.* a request for a kind of partial summary judgment that a district court actually is authorized to grant.” *Digital Grp., LLC v. Hyper Networks, Inc.*, 2022 WL 3142348, at \*4 (M.D. Tenn. Aug. 5, 2022); *see also B. Bros Packaging, Inc. v. S./Win Ltd.*, 2002 WL 424593, at \*3 (D. Minn. Mar. 18, 2002). Other courts have posited this threshold question as whether the relief sought addresses portions of a claim or would address a claim in its entirety. “Partial summary judgment is available only to dispose of one or more counts of the complaint in their entirety.” *In re Grabill Corp.*, 135 B.R. 101, 106 (Bankr. N.D. Ill. 1991); *see also Scholar Intelligent Sols., Inc. v. New Jersey Eye Ctr.*, 2016 WL 5745112, at \*4 (D.N.J. Sept. 30, 2016).

Courts in the Sixth Circuit have noted the problems with rendering summary judgment on a theory of a claim, reasoning that if the portion sought to be adjudicated is too ill-defined or confusing, they may be rendering an opinion on something that is not necessarily a claim or an issue:

When a court parses a single count too finely in pronouncing a purported partial summary judgment, it risks granting summary judgment as to something that is too fragmentary to properly be deemed even “a part of a claim” (so as to be potentially subject to summary judgment in the first place). Relatedly, a court parsing a claim too finely risks pronouncing a purported (partial) summary judgment on something that really is not susceptible to “judgment” in the traditional sense. For example, a court may be tempted to pronounce (partial) summary judgment on one of multiple theories underlying a single count, but it should think twice before doing so, because *judgment* typically is entered on *claims*, rather than on individual *theories* supporting a claim or on discrete “issues.”

*Digital Grp., LLC v. Hyper Networks, Inc.*, 2022 WL 3142348, at \*4 (M.D. Tenn. Aug. 5, 2022).

Courts in adjacent districts have held that a motion for partial summary judgment on a mere issue, similar to what the Plaintiff seeks here, cannot be granted as it is a misreading of the rule. *Biggins v. Oltmer Iron Works*, 154 F.2d 214, 216–17 (7th Cir. 1946). The kind of partial summary judgment to be avoided is one based merely on theoretical issues alone. *Digital Grp.*, 2022 WL 3142348, at \*5.

In *Digital Group*, the court made clear that a request for partial summary judgment on issues alone will cause concern. “[T]ypically mere discrete ‘issues’ are something too fragmentary to be subject to summary judgment.” *Digital Grp., LLC*, 2022 WL 3142348, at \*4. Other courts in this Circuit have also held specifically that a motion for partial summary judgment on the issue of duty is not a proper use of Rule 56(d). See *Maples v. Norfolk S. Ry. Co.*, 2007 WL 3020500, at \*3 (E.D. Tenn. Oct. 11, 2007) (“[Movant] asks this Court to go beyond the mere specifying of

uncontroverted facts and to rule conclusively on the elements of duty and breach. As such actions are outside the scope of Rule 56(d), it would be improper for this Court to grant partial summary judgment in this case.”).

Here, instead of resolving an issue or a claim, Plaintiff instead asks this Court to determine that the CSA<sup>1</sup> applies and creates specific duties. This request is one of declaratory judgment, one this Court may look beyond no matter how artfully presented. *C.f.*, *Bradshaw v. Unity Marine Corp.*, 147 F. Supp. 2d 668, 671 (S.D. Tex. 2001) (“But at the end of the day, even if you put a calico dress on it and call it Florence, a pig is still a pig.”). Merely seeking an opinion on a conclusion of law is a declaratory judgment, nothing more. *See Mikel v. Quin*, 58 F.4th 252, 259 (6th Cir. 2023).

Plaintiff argues that summary judgment is appropriate here to ensure that the CSA is applied consistently throughout the case. Plaintiff points this Court to a Third Circuit case concerning the application of law across cases in an MDL proceeding. *Home Depot USA, Inc. v. Lafarge N. Am., Inc.*, 59 F.4th 55 (3d Cir. 2023). We presume Plaintiff chose this case for its recency rather than its relevancy because it is entirely lacking in the latter. *Home Depot* is a ruling on the propriety of applying *case management orders* to the entirety of an MDL proceeding. *Id.* at 66. Case management orders are clearly distinct from substantive rulings. In fact, the court in *Home Depot* even made clear that efficiency must stand aside for meritorious claims (or defenses) to be heard. *Id.* at 66.

What’s more surprising is that Plaintiff chose to ignore relevant case law from the Sixth Circuit on the limits of the law of the case and issue preclusion doctrines. The Sixth Circuit made

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<sup>1</sup> Plaintiff in two separate instances claims it is seeking declaration that the CSA creates duties, yet refers to Ohio law. For the sake of argument, Defendant has characterized this argument as Plaintiff has set forth, and reserves response to Ohio law.

clear in *In re Nat'l Prescription Opiate Litig.*, 956 F.3d 838, 844–45 (6th Cir. 2020), that the a court's powers in an MDL are limited: “But MDLs are not some kind of judicial border country, where the rules are few and the law rarely makes an appearance. For neither § 1407 nor Rule 1 remotely suggests that, whereas the Rules are law in individual cases, they are merely hortatory in MDL ones. . . . Nor can a party's rights in one case be impinged to create efficiencies in the MDL generally.” *Id.* at 844–45.

Plaintiff's request that the law be applied “consistently” is in reality a request for a declaratory ruling that the CSA imposes certain duties on the Defendants. When a party requests nothing more than a determination of law, that request is one for declaratory judgment. Adv. Com. Notes to Rule 57 (“The existence or nonexistence of any right, duty, power, liability, privilege, disability, or immunity or of any fact upon which such legal relations depend, or of a status, may be declared.”). Here, the Plaintiff cannot move for a declaratory judgment because it must have a cognizable right at issue.

The CSA is “enforceable only by the Attorney General and, by delegation, the Department of Justice.” *Smith v. Hickenlooper*, 164 F. Supp. 3d 1286, 1290 (D. Colo. 2016) (internal citations omitted). It “does not create a private right of action.” *Id.* at 1290; *McKesson Corp. v. Hembree*, 2018 WB 340042, at \*5 (N.D. Okla. Jan. 9, 2018).<sup>2</sup> Because the alleged duties pertain only to registration requirements and are not actionable by Plaintiff in civil litigation, Plaintiff cannot establish a right to seek a declaration under the CSA. Plaintiff's request lacks the definiteness required for summary judgment or a declaratory judgment. All that is left in such a scenario is an advisory opinion. *Mikel v. Quin*, 58 F.4th 252, 259 (6th Cir. 2023).

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<sup>2</sup> Plaintiff does not make reference to Ohio law in its Motion. Defendant reserves the right to supplement this response should Plaintiff make such an argument in its Reply, if any.

The Sixth Circuit has been clear that a court may not issue an advisory opinion. *See Wheeler v. City of Lansing*, 660 F.3d 931, 940 (6th Cir. 2011) (noting Article III's prohibition against issuing advisory opinions); *see also Lowes v. Baldwin*, 2019 WL 7290504, at \*8 (S.D. Ohio Dec. 30, 2019). Since the Motion is not proper for partial summary judgment and Plaintiff lacks the requisite standing for a declaratory judgment, the Motion can be no more than an improper request for an advisory opinion that should be denied.

## **II. The Plaintiff's Request for Summary Judgment Is Without Merit.**

Even if there were a valid basis for Plaintiff's Motion, which there is not, the merits of the Motion also warrant denial. Plaintiff argues that the CSA imposes certain duties on the Defendants as *distributors*, which include, *inter alia*, to 1) provide controls against diversion, 2) implement a system to detect suspicious orders, and 3) halt shipment of such suspicious orders; and as *dispensers*, to 4) provide controls against diversion, 5) ensure only valid prescriptions were dispensed, 6) ensure their pharmacists were identifying and resolving so called "red flags", and 7) finally make use of the data in their possession. Motion, 2. While Plaintiff seeks a ruling that would create what it considers "consistent" or "uniform" law in this MDL by applying portions of this Court's since-clarified ruling,<sup>3</sup> it would have the effect of rendering this jurisdiction inconsistent with others considering this exact same question.

*a. Distributor duties are not enforceable by Plaintiff and non-existent.*

As to distributors, courts have ruled that their duties are distinct from dispensers when it comes to effective controls and suspicious order monitoring:

Not only do distributors have no ability to stop pills on a prescription-by-prescription basis and none of the expertise with which to determine whether prescriptions are good or bad, they also

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<sup>3</sup> Specifically, Plaintiff ignores that this Court clarified its prior ruling on the duties imposed by the CSA by holding: "Defendants are correct that there is no explicit requirement that they use the prescription data they collect to prevent diversion." *In re Nat'l Prescription Opiate Litig.*, 2020 WL 5642173, at \*3 (N.D. Ohio Sept. 22, 2020).

have none of the coercive powers of investigation that law enforcement has to determine whether pharmacies are fulfilling their duties under the CSA.

*City of Huntington v. AmerisourceBergen Drug Corp.*, 2022 WL 2399876, at \*65 (S.D.W. Va. July 4, 2022).

Furthermore, Defendants do not dispute that the CSA specifies identification and reporting duties with which registrants must substantially comply to receive and maintain licenses to manufacture or distribute controlled substances; but as set forth above, these duties are not legally actionable by civil plaintiffs. Defendants may have duties under these laws, but any breach, if one occurred, is actionable by the DEA, not Plaintiff. *See* 21 U.S.C. § 823(a), (b) (directing that the DEA “shall register an applicant” to manufacture or distribute “controlled substances” unless it determines that the “issuance of such registration is inconsistent with the *public* interest”); 21 U.S.C. § 823(e) (emphasis added); 21 C.F.R. § 1301.71(a) (instructing DEA to consider certain factors, including the applicant’s “maintenance of effective controls against diversion” when determining the “*public* interest” for purposes of registration decisions) (emphasis added); 21 C.F.R. § 1301.71(a) (stating that the DEA should use “the security requirements,” which provide “standards for the physical security controls and operating procedures necessary to prevent diversion” to determine whether registrants have provided “effective controls”). The DEA, not Plaintiff, is equipped and situated to weigh the “public interest” in registration decisions.

As to the second duty sought by the Plaintiff concerning suspicious order monitoring, the CSA requires only that registrants to “design and operate a system to disclose to the registrant suspicious orders of controlled substances” and “inform” the DEA of “suspicious orders when discovered by the registrant.” 21 C.F.R. § 1301.74(b). The law and regulations leave the design and implementation of suspicious order monitoring systems in each instance to registrants—not

the federal or state government. “The regulations do not prescribe any particular form or style of monitoring system.” *US v. \$463,497.72 in U.S. Currency from Best Bank Acct. #£XXX2677*, 853 F. Supp. 2d 675, 681 (E.D. Mich. 2012) (hereinafter *\$463,497.72*).

Consistent with their plain meaning, the CSA provisions at issue serve only to enable the DEA to make licensing determinations—not to impose legal duties that run to parties that can be enforceable through claims in civil litigation. Indeed, the regulations specify that “substantial compliance . . . may be deemed sufficient” by “the [DEA] after evaluation of the overall security system and needs of the applicant or registrant.” 21 C.F.R. § 1301.71(b). This “substantial compliance” standard, left to the DEA’s discretion, confirms that the “effective controls” provisions apply only for purposes of registration. They do not establish any independent duties running to and enforceable by civil plaintiffs.

As to the duty not to ship, even if the provisions imposing an effective controls duty on Defendant were enforceable by the Plaintiff, they say nothing about a no-shipping duty. *See* 21 C.F.R. § 1301.74(a). They may instruct registrants about other steps to take before placing a shipment, such as requiring distributors to “make a good faith inquiry” into purchaser’s registration “[b]efore distributing a controlled substance” or requiring prior written requests before distributing samples. *Id.* § 1301.74(d). Because neither the CSA nor the implementing regulations mention a no-shipping duty, this Court may not rewrite them to impose such a requirement.

Other courts have rejected the same no-shipping argument advanced by Plaintiff here. *See State of Rhode Island*, 2020 WL 2315956, at \*3 (R.I. Super. May 5, 2020) (This supposed “[no-shipping] requirement does not appear in the text of the [federal and state] CSAs or the associated regulations.”); *\$463,497.72*, 853 F. Supp. 2d at 685. *See also \$463,497.72*, 853 F. Supp. 2d at 682



(“The DEA was aware that it was standard practice in the industry to file suspicious order reports while continuing to ship products, and that practice had been approved by the DEA.”).

*b. Duties of Defendants as dispensers do not exist as stated by Plaintiff.*

Plaintiff seeks that this Court impose certain duties on the Defendants as pharmacies. Yet, the portions of its past, later clarified, ruling do not support the three duties Plaintiff seeks to establish by partial summary judgment here.

First, the duty of effective controls concerns Ohio law, not the CSA, which is what Plaintiff is asking the Court to construe here. These duties seem to rest on the fourth bullet point on page 2 of Plaintiff’s Motion, which misstates this Court’s ruling at *In re Nat’l Prescription Opiate Litig.*, 477 F. Supp. 3d 613 (N.D. Ohio 2020), clarified on denial of reconsideration, 2020 WL 5642173 (N.D. Ohio Sept. 22, 2020). The excerpt used to support these requests restates this Court’s opinion as to *Ohio* law, not the federal CSA, though the Motion pleads only for application of the CSA.

Second, there is nothing in the cited portions of the previous ruling that relates to a duty to take appropriate measures concerning valid prescriptions. It seems that the Plaintiff is resting its proverbial hat on the portions of the prior ruling concerning the Defendant’s duty to use information its pharmacists collect. This is directly contrary to what this court definitively ruled. “Similarly, Defendants are correct that there is no **explicit** requirement that they use the prescription data they collect to prevent diversion.” *In re Nat’l Prescription Opiate Litig.*, 2020 WL 5642173, at \*3 (N.D. Ohio Sept. 22, 2020) (emphasis added). Effectively, Plaintiff has asked that this Court apply the first iteration of a ruling it later clarified, rather than the clarified one. This is not how precedent works in courts of the United States. To the extent the Motion seeks to

establish the last three duties (*see* (b)(ii), (b)(iii), and (b)(iv)) from that statement, those requests should be denied.

As to the request seeking that this Court determine that pharmacies conduct business so that their pharmacists can resolve red flags (*see* (b)(iii)), this request seems to rest on the excerpt from the Court's lengthy opinion concerning a motion to dismiss related to Ohio state law, not the CSA. Whether Ohio state law applies and how it applies are not arguments made by the Plaintiff. Instead, Plaintiff focuses on the federal CSA. Accordingly, as the Plaintiff has made a request which is internally inconsistent, any ruling granting it as requested would be incoherent. For those reasons, this Court should deny the Motion.

### **III. Conclusion**

For the reasons stated above, Defendants respectfully request that the Court deny Plaintiff's Motion and take such other and further relief as may be necessary.

Dated: March 9, 2023

Respectfully submitted,

**The Kroger Co., Kroger Limited  
Partnership I, Kroger Limited  
Partnership II,**

**By counsel,**

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**CERTIFICATE OF SERVICE**

I, the undersigned, hereby certify that on March 9, 2023, the foregoing document was filed with the Clerk of Court using the CM/ECF system which will send notice to all counsel of record. Copies of this document may be obtained through the CM/ECF system.

/s/ Ronda L. Harvey  
Ronda L. Harvey, Esq. (WVSB 6326)